

REMARKS

Applicants' instant Amendment After Final is submitted in response to the outstanding Office Action mailed from the US Patent Office on April 26, 2007, in the above-identified application. A Petition For Extension of Time accompanies the Amendment After Final, which extends the time for applicants response one (1) month, up to and including August 26, 2007. Claims 1-8 remain pending hereafter, where claim 1 is the sole independent claim. Dependent claim 2 has been amended in response to the "Claims Objections" set forth at paragraph 2 of the outstanding Office Action, and each of the pending claims has been amended in its preamble to make clear that the ultrasonic probe is actually an "ultrasonic probe for an endoscope." Reconsideration is respectfully requested.

Response To Rejections Under 35 USC § 103

At paragraphs 3-12 of the outstanding final Office Action, the Examiner rejected claims 1-5, 7 and 8 under 35 USC § 103(a) over commonly-owned US Patent No. 5,176,140, to Kami, et al. (Kami), in view of US Patent No. 5,722,644, to Kinoshita, et al. (Kinoshita). The Examiner asserts that Kami discloses an ultrasonic probe (Fig. 35) having a transducer formed of sequential lamination. The Examiner further describes sequential lamination as comprising, with respect to Kami, an acoustic lens (71), an acoustic matching layer (62), a piezoelectric element (61) and a backing member (63), where the backing member is for attenuating ultrasonic waves (col. 14, 10-13) and the acoustic lens arranged on the piezoelectric element (Fig. 35). The Examiner then states that Kami does not disclose "expressly" that the backing (damping layer) contains a synthetic rubber with a mixture including acrylonitrile-butadiene rubber, ethylene-

propylene terpolymer, and at least inorganic fine powders, but that Kinoshita teaches the use of vibration-damping material of a mixture including acrylonitrile-butadiene rubber, ethylene-propylene terpolymer, and at least inorganic fine powders, so that at the time of the invention it would have been obvious to combine Kinoshita's vibration-damping material with Kami's ultrasonic vibrator 5 for the benefit of self-adhesive.

In response, applicants respectfully assert that independent claim 1 is not obvious under 35 USC § 103(a) by Kami in view of Kinoshita for at least the following reasons. Initially, and based on a careful analysis of Kami and Kinoshita, applicants respectfully assert that it is improper to combine the references under 35 USC 103(a) for lack of proper motivation or an express reason for doing so under the law. Applicants find no teaching, suggestion or motivation in either Kami or Kinoshita for making such a combination, and the stated benefit of "self adhesive properties of the [Kinoshita] material" (col. 1, lines 65-67), is not a sufficient express reason for doing so under the law, and therefore fails to establish a prima facie case of obviousness under Section 103(a).

The US Supreme Court has recently issued its opinion in KSR Int'l Co. v. Teleflex, Inc., No. 04-1350 (US Apr. 30, 2007), recognizing that a showing of "teaching, suggestion, or motivation" (TSM) to combine the prior art to meet the claimed subject matter could provide insight under Section 103(a). While the Supreme Court held that TSM should not be applied rigidly, it further held that the analysis supporting a rejection under 103(a) should be explicit and identify a reason that would have prompted a skilled artisan to combine the prior art elements. While the Examiner has indicated that the combination would have been obvious "for the benefit of self-adhesive properties of the material" (col. 1, lines 65-67), applicants, in view of the law, and with all due respect, assert that the Examiner has not his burden of establishing a proper

teaching, suggestion or motivation to combine, or any other reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. Id. Kinoshita's pre-shaped, self-adhesive vibration-damping member for a deformed portion has no relation to laminated transducers formed with a damping layer for use in an ultrasonic probes. The two references are not in the same field of endeavor, and are not disclosed to remedy similar shortcomings.

As understood by applicants, Kinoshita discloses a pre-shaped, self-adhesive vibration-damping member for a deformed pipe-branch portion with a contact shape shaped to fit the shape of the deformed portion, and a releasing film. Kami discloses an ultrasonic probe for use in an ultrasonic endoscope that includes an ultrasonic vibrator. Kami does not include or disclose a backing member, still less a backing member comprising a vibration damping material that is water and drug or chemical resistive, mechanically strong for frequent use within an ultrasonic probe for an endoscope. Kinoshita's pre-shaped vibration, self adhesive damping member for a deformed pipe-branch portion of machine components was developed in order to realize a damping member that is readily adhered, and mentions nothing about endoscopes, ultrasonic transducers, etc. Kami's ultrasonic transducer and Kinoshita's pre-shaped vibration damping member were developed to support completely different endeavors. Applicants' backing member as claimed is not equivalent to the Kinoshita self-adhered pipe branch backing member, shaped in advance to fit the shape of the Kinoshita deformed portion, nor Kami's ultrasound probe.

Applicants' independent claim 1 sets forth an ultrasonic probe for an endoscope comprising an ultrasonic transducer. The ultrasonic transducer comprises, by sequential lamination, an acoustic lens, an acoustic matching layer, a piezoelectric element and a backing

member. The backing member attenuates ultrasonic waves and contains a synthetic rubber having a mixture including acrylonitrile-butadiene rubber (NBR), ethylene-propylene terpolymer (EPDM), and at least inorganic fine powders.

The ultrasonic probe for an endoscope of the present invention is designed and intended for use with an endoscope, i.e., the ultrasonic probe is inserted into the body cavity. As such, the ultrasonic probe for an endoscope is placed in close contact with the moistened body wall in order to obtain ultrasonic tomographic images, or immersed in a medium for transmitting ultrasonic waves. In greater detail, a) the vibration damping material that forms the ultrasonic probe for an endoscope is exposed to the moisture or water during observing within the body cavity. The endoscope is generally repeatedly used, and at such using, exposed or subjected to washing and sterilization. Thus, b) chemical agents or heat to which the ultrasonic probe with endoscope must necessarily be applied also to the vibration-damping material forming the ultrasonic probe for an endoscope. And since the vibration damping material is used for the ultrasonic probe, c) it is affected by the ultrasonic waves.

Since the endoscope is used repeatedly, the vibration-damping material that comprises the ultrasonic probe for an endoscope must, by its nature, maintain a highly-stable shape to prevent it from being deformed under the above-mentioned conditions [a), b) and c)]. More particularly, the shape must be maintained so that the characteristics of the ultrasonic waves to be sent and/or received do not unacceptably vary by the swelling or deforming thereof, due to the exposure to the liquid, or deform thereof due to the exposure to the heat or the ultrasonic waves as already mentioned. If such swelling or deforming conditions occur during operation, the intended performance of the ultrasonic probe for an endoscope as designed cannot be realized.

The longevity or ability to repeatedly use the ultrasonic probe for an endoscope without the claimed vibration-damping material is not possible. Put another way, the vibration-damping material that comprises the ultrasonic probe for an endoscope must be water-resistive, chemical agent and/or heat resistive and mechanically strong in light of the above-mentioned conditions [a), b) and c)]. Hence, the inventors had, after various attempts to prepare a water-resistive, chemical agent and/or heat resistive and mechanically strong vibration damping member, concluded that a mixture including acrylonitrile-butadiene rubber (NBR), ethylene-propylene terpolymer (EPDM) and at least inorganic fine powders recited by the language of claim 1 is the most suitable material for displaying water-resistive, chemical and/or heat resistive in addition to its vibration-damping characteristics.

While Kinoshita discloses a pre-shaped, self-adhesive vibration-damping member for a deformed pipe-branch portion with a contact shape shaped to fit the shape of the deformed portion, and a releasing film, it does not refer at all to addressing the above-mentioned conditions a), b) or c). Hence combining Kinoshita with Kami as asserted in the rejection of claim 1 under Section 103(a) cannot realize applicants' invention as claimed, and applicants respectfully request that the Examiner withdraw the rejection and allow independent claim 1.

At paragraph 6 of the outstanding Office Action, the Examiner rejected claim 2 under 35 USC § 103(a) as obvious by Kami in view Kinoshita, asserting that while neither Kami nor Kinoshita disclose the backing member with a hardness property of 80 to 100 degrees in the A scale in conformity with JISK6253, and an ultrasonic absorbing coefficient of 10dB/mm or more at a frequency of 5MHz, but that it has long been held that it is obvious to discover optimum or workable ranges by routine investigation, rendering the claim 2 subject matter obvious. The Examiner cites In re Aller, 105 USPQ 233 (CCPA 1955) to support the rejection of claim 2.

Applicants respectfully disagree with the Examiner's characterization of the instant facts with the law of Aller, which stands for "optimization" of ranges. In Aller, the Appellant's claimed process on appeal therein was found to be identical with a process of the prior art, except for being implemented in a higher temperature range, and within a higher range of sulphuric acid concentrations. The CCPA in Aller stated that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Aller at 235. But the use of Kinoshita as the secondary reference is distinguishable from the facts of Aller. There is no range, or optimized range taught by Kinoshita, taking the instant facts from within the precedential control of Aller.

Kinoshita merely discloses synthetic rubber as part of its self-adhered pipe branch backing member, but discloses no range of hardness, still less a range of 80 to 100 degrees in the A scale to conform with JISK6253. Kinoshita's only limitation with respect to its compound including ABR includes that it display a specific gravity range of 1.6-2.8, and an adhesive strength range of 0.5-2.0 Kg/25 mm below. Because the Kinoshita reference is not directed to the field of ultrasonic probes, nor ultrasonic probes for an endoscope, because it does not refer to hardness properties, and still less a hardness property of between 80 and 100 degrees in the A scale, and because it does not refer to an ultrasonic absorbing coefficient of 10 dB/mm at 5MHz, the rejection of claim 2 is improper.

US law and practice requires that a particular parameter must first be recognized as a result-effective variable, i.e., a variable that achieves a recognized result, before determination of an optimal or workable range of the variable might be characterized as a "routine experimentation" under the law. In re Antonie, 195 USPQ 6 (CCPA 1977). Again, because there is no reference in Kinoshita of the claimed ranges (limitations), i.e., a result-effective variable,

the proposition that the claim 2 subject matter is within the skilled artisan's scope of routine experimentation is unsupportable under the law. Applicants, therefore, respectfully request that the rejection of claim 2 under 35 USC §103(a) in view of Kami and Kinoshita be withdrawn, and claim 2 allowed.

Claim 3 was rejected by the asserted combination of Kami and Kinoshita under Section 103(a) according to claim 1 (at paragraph 7), claim 4 was rejected by the asserted combination of Kami and Kinoshita under Section 103(a) according to claim 1 (at paragraph 8), claim 5 was rejected by the asserted combination of Kami and Kinoshita under Section 103(a) according to claim 1 and claims 7 and 8 were rejected by the asserted combination of Kami and Kinoshita under Section 103(a) according to claim 1. Applicants respectfully assert that the claims 3, 4, 5, 7 and 8 are not obvious under Section 103(a) by the asserted combination of Kami and Kinoshita for at least the reasons set forth above for the patentability of independent claim 1 from which they depend, and respectfully request withdrawal of the rejection of those claims thereunder.

At paragraph 11 of the outstanding final Office Action, the Examiner rejected claim 6 under 35 USC § 103(a) as obvious by Kami in view Kinoshita, and further in view of US Patent No. 4,281,550 to Erikson, and still further in view of US Patent No. 6,781,287 to Dam, et al. The Examiner states that neither Kami nor Kinoshita disclose that the acoustic medium is water with low attenuation to ultrasonic waves, but that Erikson teaches an ultrasonic probe with an exterior cap that immerses the transducer in an acoustic medium of oil (col. 3, lines 54-57), and Dam teaches an ultrasound probe with an exterior cap and immersion in oil (33), and that oil displays a low attenuation to ultrasonic waves (col. 3, lines 27-31). The Examiner then asserts that it would have been obvious to combine Erikson and Dam with Kami's ultrasonic transducer as modified by Kinoshita for the benefit of using an acoustic medium with a material that is

matched to the ultrasound transmissive properties of the human body (col. 3, lines 54-57 of Erikson).

In response, applicants respectfully assert that the proposed combination of Erikson and Dam with Kinoshita and Kami for the stated reason for making such a by-four combination of references is improper. The skilled artisan at the time of the invention would not have looked to Erikson, Dam or Kinoshita. But even *assuming arguendo* that there is, or could be some reason or proper motivation to combine the four references under the law, the combination would not read on applicants' invention as per claim 6. Claim 6 recites: an ultrasonic probe for an endoscope according to Claim 1, wherein the acoustic medium is aqueous solution that imposes a low attenuation on ultrasonic waves arriving at a surface of the ultrasonic transducer, and wherein the aqueous solution is obtained by adding an additive to the water, or oil that displays a low attenuation to ultrasonic waves. The cited Erikson text states that it's housing may be filled with oil. Applicants do not claim an array contained in a housing 204 which includes an ultrasound transmissive window 206, where the housing is filled with an ultrasound transmissive fluid 208 such as castor oil, assertedly matched to the ultrasound transmissive properties of the human body, as found in Erikson's col. 3, lines 27-31.

Claim 6 does not claim "oil" *per se* or like material, but an acoustic medium comprising an aqueous solution of water or oil, with an additive that displays a low attenuation to ultrasonic waves. For that matter, applicants question whether castor oil can be matched to the ultrasonic properties of the human body as stated by Erikson. The statement appears to be overly broad, and possibly wrong because as is readily known to the skilled artisan, the ability to use ultrasonic diagnostics for medical evaluation is based on differences in the ultrasound transmissive properties of the various tissues of the human body. If different tissue did not reflect ultrasound

waves differently, there could not be ultrasonic diagnostics, so applicants disagree that one element of castor oil "matches" all human body tissue impedance. Applicants, therefore, respectfully assert that claim 6 is not obvious in view of the asserted Kami, Kinoshita, Erikson and Dam combination for these reasons, and at least the reasons set forth above in response to the Section 103(a) rejection of claim 1 in view of Kami and Kinoshita, from which claim 6 depends, and request withdrawal of the claim 6 rejection thereunder.

In concluding, applicants respectfully assert that each of claims 1-5, 7 and 8 are patentably distinct from Kami and Kinoshita, whether alone or in combination, and claim 6 is patentably distinct from Kami, Kinoshita, Erikson and Dam, whether alone or in combination, under Section 103(a), and respectfully request withdrawal of the rejection of those claims under section 103(a). If the Examiner believes that a telephone conference with applicants' attorneys would be advantageous to the disposition of this case, the Examiner is asked to telephone the undersigned.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John F. Vodopia", is written over the typed name.

John F. Vodopia
Registration No.: 36,299
Attorney for Applicants

SCULLY, SCOTT, MURPHY & PRESSER, P.C.
400 Garden City Plaza, Suite 300
Garden City, New York 11530
(516) 742-4343

JFV:tb